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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,723	03/19/2004	Ehud J. Schmidt	GEMS8081.204	2722
27061	7590	01/26/2010		
ZIOLKOWSKI PATENT SOLUTIONS GROUP, SC (GEMS)			EXAMINER	
136 S WISCONSIN ST			WEATHERBY, ELLSWORTH	
PORT WASHINGTON, WI 53074			ART UNIT	PAPER NUMBER
			3768	
			NOTIFICATION DATE	DELIVERY MODE
			01/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/708,723	Applicant(s) SCHMIDT, EHUD J.	
	Examiner ELLSWORTH WEATHERBY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 30, the claimed "further comprising receiving tracking feedback from the tracking coil with the auto-expandable former compressed within the sheath while navigation to a target anatomy" is not clear. That is, the parent claim calls for retracting the sheath. Thus, claim 30 appears to call for an additional step of tracking the device while the auto-expandable former is compressed within the sheath even after the sheath is retracted. Appropriate correction is required

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1 and 4-16** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Atalar et al. (USPN 6,628,980).

6. **Regarding claims 1, 4 and 16**, Atalar et al. (hereinafter Atalar) teaches a probe for acquiring data in a magnetic resonance imaging (Abstract; Figs. 1-18), comprising: A self expanding distal head insertable into a subject's vascular system to be imaged and constructed to permit fluid or blood flow therethrough (col. 3, lines 55-67; col. 4, lines 1-5; col. 14, ll. 30-65; col. 19, lines 50-56 See also Distal head of Figure 6D). Here, the distal region comprises an imaging coil (644), comprising a plurality of RF coils (607a, 607b) that are expandable when tubular member (698) is retracted. For example, Atalar teaches a multi coil MRI probe comprising an expandable probe (870) that is advanced so that the RF coil (804) protrudes from the sleeve (868) (col. 16, ll. 29-37). In the expanded state, the coil (804) forms a gap between the coil (804) and the nested expandable probe (870). Another embodiment that reads on the present claim 1 is described by Figures 8A-B or 9A-B. Here, a loop imaging coil (972) is inserted into a loopless imaging coil sleeve (974) (col. 16, l. 50-col 17, l. 24). Furthermore, the gap between the housing and the coil (804) is configured to increase RF sensitivity away from the probe (col. 16, l. 64- col. 17, l. 24). Also, the MRI sleeve and probe may comprise one or more imaging coils (col. 16, ll. 59-63; col. 17, ll. 19-24). Therein, Atalar teaches that the combination provides a sensitivity profile combining the strengths of both types of coils is achieved.

7. **Regarding claim 5**, Atalar also teaches that the device further comprises at least one tuning capacitor connected to the plurality RF coils, the at least one tuning capacitor configured to tune the plurality RF coils (col. 17, lines 40-44).

8. **Regarding claims 6-9**, Atalar also teaches Atalar et al. '980 further teaches a shaft connected to the housing and constructed to position the housing within the subject to be imaged (col. 4, lines 40-43). Atalar et al. '980 also teaches a retractable sheath constructed to enclose the housing during insertion into the subject and translation to a target tissue to be imaged and further constructed to be retracted by a user to allow the housing to expand when proximity to the target tissue is reached (col. 16, lines 29-31). Atalar et al. '980 also teaches that the sheath is constructed to enclose the housing during insertion into the subject and translation to a target tissue to be imaged and further constructed to be retracted by a user to allow the housing to expand when proximity to the target tissue is reached (col. 15, lines 66-67; col. 16, 1-11; col. 16, lines 29-31). Atalar et al. '980 also teaches that the sheath is formed of a material that applies a compression force upon the housing and the plurality RF coils during insertion into the subject and translation to the target tissue to be imaged, and wherein the housing is constructed of material to automatically expand the plurality RF coils when the compression force is removed, and further, that the sheath has a shaft that exceeds a distance from an insertion point to the target tissue to be imaged (col. 15, lines 66-67; col. 16, 1-37).

9. **Regarding claims 10-11**, Atalar teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first

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and second RF loop coils, comprising a nitinol and insulating material (col. 14, ll. 30-67; refs. 607A-B).

10. The Examiner has applied this type of rejection because the present claim language is broad and is open to plural interpretations. That is, Atalar discloses as well known that loop imaging coils provide near field imaging with increased sensitivity distributed across their length (col. 17, ll. 1-15). It is within reason that one of ordinary skill in the art would interpret the gap formed between the plurality of expanded RF coils and the housing to be met by the expanded loop coils of Atalar. However, if it is interpreted that Atalar does not expressly teach the gap formed between the plurality of expanded RF coils, there is nothing in disclosure to show why the multiple expandable coils, comprising nitinol surrounded by an insulating material, of Atalar for is not an obvious variant of the present application's gap formed between the RF coils and housing, where the housing comprises nitinol and the gap comprises an insulating material because both achieve the same function of increasing RF sensitivity away from the probe.

11. **Claims 2-3, 26-28, 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Nevo et al. (USPN 6,516,213).

Atalar et al. '980 teaches all the limitations of the claimed invention (see above) except for expressly teaching that a tracking coil is configured to transmit tracking

signals for gating data acquisition. Atalar also does not expressly teach that the device is an intra-cardiac device.

In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils, which are configured to transmit tracking signals for gating data acquisition (col. 14, ll. 21-40; col. 15, ll. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, l. 55- col. 14, l. 18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the expandable RF probe of Atalar in view of the tracking coils for gating acquisition of Nevo. The motivation to modify Atalar in view of Nevo would have been to provide accurate readings of position or orientation of an intra-cardiac probe throughout the procedure where the position data is acquired using known tracking coils, as taught by Nevo.

12. **Claims 17 and 19-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213).

13. Gupta et al. (hereinafter Gupta) teaches an MRI apparatus (Abstract: Figures 1-4), comprising: a magnetic resonance imaging (MRI) system having a plurality of gradient coils positioned about bore of a magnet to impress a polarizing magnetic field and an RF transceiver system and an RF switch controlled by a pulse module to

transmit RF signals to an RF coil assembly to acquire MR images (col. 3, ll. 42-65), the RF assembly being used to track the motion of a medical instrument (col. 3, ll. 26-41).

14. Gupta does not expressly teach that the RF coil assembly comprises an intra-cardiac catheter configured for insertion into a blood flow and constructed to automatically expanded position from a compressed position; a plurality of RF coils connected to the catheter and configured to acquire MR data; a tracking coil connected to the catheter and configured to acquire MR data; a tracking coil connected to the catheter and configured to indicate RF coil assembly location and movement within an imaging subject; wherein the tracking coil is configured to transmit signal indicating the location and movement of the RF coil assembly to the MRI system to facilitate MR data acquisition gating; and wherein the MRI system is configured to gate MR data acquisition during imaging based on the location and movement of the RF coil assembly.

15. In a related field of endeavor, Atalar et al. (hereinafter Atalar) teaches a probe for acquiring data in a magnetic resonance imaging (Abstract; Figs. 1-18), comprising: A self expanding distal head insertable into a subject's vascular system to be imaged and constructed to permit fluid or blood flow therethrough (col. 3, lines 55-67; col. 4, lines 1-5; col. 14, ll. 30-65; col. 19, lines 50-56 See also Distal head of Figure 6D). Here, the distal region comprises an imaging coil (644), comprising a plurality of RF coils (607a, 607b) that are expandable when tubular member (698) is retracted. For example, Atalar teaches a multi coil MRI probe comprising an expandable probe (870) that is advanced so that the RF coil (804) protrudes from the sleeve (868) (col. 16, ll. 29-37). Atalar

further teaches that the expanded diameter substantially matches an inner diameter of a target tissue in which the probe is placed (claim 49). Atalar teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first and second RF loop coils, comprising a high memory nitinol and insulating material (col. 14, ll. 30-67 refs. 607A-B: Regarding this limitation, see above obvious variation argument).

16. Atalar does not expressly teach that the catheter is an intra-cardiac catheter or that the tracking coil is configured to transmit tracking signals for gating data acquisition.

In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils configured to transmit tracking signals for gating data acquisition (col. 14, ll. 21-40; col. 15, ll. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, l. 55- col. 14, l. 18).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the MRI system for tracking medical devices of Gupta in view of the expandable RF probe of Atalar and the tracking coil for gating acquisition of Nevo. The motivation to modify Gupta in view of Atalar and Nevo would have been to provide dynamic intra-cardiac imaging using known devices or techniques.

Response to Arguments

18. Applicant's arguments, filed 9/24/2008, with respect to the finality of the 7/24/2008 Office Action have been fully considered and are persuasive. The previous grounds of rejection has been withdrawn. Furthermore, the 3/25/2008 Restriction has been withdrawn. That is, claims 1-17, 19-28, 30-32 are currently pending.

19. Applicant's arguments filed 9/11/2007 with respect to claims 1-17, 19-28, 30-32 have been considered but are moot in view of the new ground(s) of rejection.

20. Here, Atalar has been applied as a 103 or 102 type rejection because Applicant includes claim language that is open to various interpretations. That is, "a gap formed between the plurality of RF coils and the housing..." is an ambivalent claim limitation. That is, the limitation leads one of ordinary skill in the art to interpret the claim to mean a gap formed between the plurality of RF coils and the housing from the compressed state. This is consistent with teachings in the prior art regarding near field imaging, where the RF coils are displaced radially. However, if the claim is interpreted to mean a space between a RF coil and member to which it is attached then the Examiner stands that the presently claimed structure is a mere obvious variant of Atalar. As noted above, the Examiner agrees that the Finality of the rejection after a Restriction was determined improper by the 09/24/2009 arguments after final. Furthermore, the requirement for restriction has been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768